10/593,318

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 159035-5 DK	FOR FURTHER ACTION	See item 4 below
International application No. PCT/IL2005/000300	International filing date (day/month/year) 16 March 2005 (16.03.2005)	Priority date (day/month/year)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant OR-NIM MEDICAL LTD.		

1.	. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).			
2.				
	to the international preliminary re		he International Searching Authority should be read as a reference r I) instead.	
3.	This report contains indications re	elating to the following items	:	
	Box No. I	Basis of the report		
	Box No. II	Priority		
	Box No. III	Non-establishment of opini applicability	on with regard to novelty, inventive step and industrial	
	Box No. IV	Lack of unity of invention		
	Box No. V		Article 35(2) with regard to novelty, inventive step or industrial explanations supporting such statement	
	Box No. VI	Certain documents cited		
	Box No. VII	Certain defects in the intern	national application	
	Box No. VIII	Certain observations on the	international application	
4.	4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).			
			Date of issuance of this report 18 September 2007 (18.09.2007)	
	The International Burea 34, chemin des Colo 1211 Geneva 20, Swi	mbettes	Authorized officer Simin Baharlou	
Facsimile No. +41 22 338 82 70			e-mail: pt09.pct@wipo.int	

Form PCT/IB/373 (January 2004)

DATENT COOPERATION TREATY

REC'D 27 MAR 2006

		PATENI	COOPE	(Allon little	· · · ·		PCT
rom the	ONAL SEARCHT	NG AUTHORITY				WIPO	FOI
NTERNATIONAL SEARCHING AUTHORITY To: Svetlana Shtadler REINHOLD COHN AND PARTNERS			PC'	Γ			
P.O. BOX 4060				WR	ITTEN OPIN	ION OF THE	
TEL AVIV	, ISRAEL 61040			INTERNATIO	NAL SEARC	HING AUTH	IORITY
					(PCT Rule	13 <i>bis</i> .1)	
				Date of mailing (day/month/year)		MAR 200	6
Applicant's	or agent's file ref	erence		FOR FURTHER	ACTION See paragraph 2	below	j
159035-5 I)K					lay/month/year)	
Internation	al application No.	Internatio	nal filing date	(day/month/year)	Priority date (a	ay/monin/year)	
PCT/IL05/	00300	16 March	2005 (16.03.2	2005)	L		
Internation	al Patent Classific	eation (IPC) or both nation	onal classifica	tion and IPC			
IPC(7): A6	1B 08/00 and US	Cl.: 600/438					
Applicant							
OR-NIM N	MEDICAL LTD.						
1. This c	pinion contains in	ndications relating to the	e following ite	ms:			
	Box No. I	Basis of the opinion					
	Box No. II	Priority					
	Box No. III	Non-establishment of		regard to novelty, inve	entive step and in	dustrial applicab	ility
	Box No. IV	Lack of unity of inver					
	Box No. V	Reasoned statement u applicability; citation	inder Rule 43 <i>l</i> is and explanat	bis.1(a)(i) with regard tions supporting such	to novelty, inver statement	tive step or indu	strial
	Box No. VI	Certain documents ci	ted				
	Box No. VII	Certain defects in the	international	application			
	Box No. VIII	Certain observations	on the interna	tional application			
If a Inter Auth that	national Prelimin nority other than t written opinions o	national preliminary exi lary Examining Author his one to be the IPEA of this International Sear	and the chos rehing Authori	en IPEA has notified ity will not be so cons	the International	l Bureau under I	Rule 66.1 <i>bis(b</i>)
IPE.	If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220.			submit to the date of mailing			
		e notes to Form PCT/IS.	A/220.				
		Cat - YOA / TIG	Date of con	npletion of this opinio	Authorized	officer	
Name a	nd mailing address Mail Stop PCT, A	s of the ISAV US ttn: ISA/US	1		Marvin Lat		
1	Commissioner for		17 January	2006 (17.01.2006)	~		74. 1

17 January 2006 (17.01.2006)

Telephone No. 703-308-0858

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Form PCT/ISA/237 (cover sheet) (April 2005) Form PCT/ISA/237 (cover sheet) (April 2005)

International application No.

PCT/IL05/00300

В	x No.	I Basis of this opinion
1.	With re	egard to the language, this opinion has been established on the basis of:
	∇	the international application in the language in which it was filed
		a translation of the international application into, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2.	With re	egard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed ion, this opinion has been established on the basis of:
	a.	type of material
		a sequence listing
		table(s) related to the sequence listing
	b.	format of material
	U.	on paper
l		
		in electronic form
	c.	time of filing/furnishing
		contained in the international application as filed.
		filed together with the international application in electronic form.
		furnished subsequently to this Authority for the purposes of search.
3	ı. 🗀	In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
1	I. Addi	itional comments:
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Form PCT/ISA/237(Box No. I) (April 2005)

Form PCT/ISA/237 (Box No. V) (April 2005)

International application No. PCT/IL05/00300

INTERNATIONAL SECTION			- industrial
Box No. V Reasoned statement under Rule applicability; citations and expla	43 <i>bis</i> .1(a)(i) nations supp	with regard to novelty, inventive step of orting such statement	industrial
1. Statement			
	Claims	5-8,10-35,38-39,42-48,55 - 70	YES
Novelty (N)		1-4,9,36-37,40-41,49-54	NO
			YES
Inventive step (IS)		18-20, 38-39,45-46,60-65 1-17,21-37,40-44,47-59, 66-70	NO
	Clanis	1-17,21-37,30-17,37-33,40-73	
Industrial applicability (IA)		1 - 70	YES
	Claims	NONE	NO
2. Citations and explanations:			
Please See Continuation Sheet			
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I .			

International application No. PCT/IL05/00300

 Supplemental Box In case the space in any of the preceding boxes is not sufficient.
V. 2. Citations and Explanations: Claims 1 - 4, 9, 36 - 37, 40 - 41, 49 - 54 lack novelty under PCT Article 33(2) as being anticipated by Sfez et al (US6815694) which teaches that an optical transmission and detection unit may be operated in a method using a system having ultrasound acoustic tagging of a targeted region such that the optical illumination and detection unit 14 and 18 may be operated with scanned ultrasound optimized to differing focal depths may be operated with at least two different phase sequences soas to change effective photon path lengths and measure differences in absorption/attenuation so that the control unit may act to measure the blood volume or oxygen saturation in a region of interest.
Claims 5-8,10, 27 - 35, 68 - 70 lack an inventive step under PCT Article 33(3) as being obvious over Sfez et al in view of Godik (US6,002,958) since whereas the former is silent as to duty cycle variations in the acoustic radiation, it would have been obvious in view of the latter col. 5 lines 12 - 34 to vary the duty cycle as shown in Figs. 2 - 3 in order to optimally differentiate differing tissue types, and to provide a common opto-acoustic support unit encircling the test subject and having a plurality of selectable light ports as shown for example in Fig. 4.

Claims 11 - 17,48,55- 57, 67 lack an inventive step under PCT Article 33(3) as being obvious over Sfez et al in view of Tomlinson, Jr. et al (US5,212,667) insofar as whereas the former is silent as to photon tagging efficiency, it would have been obvious in view of the latter col. 5 line 42 - col. 6 line 60 to use ultrasound at different amplitudes in the pulse sequences of the former during measurement in order to provide differing photon efficiencies in order to provide a reference standard for measurement, and to use speckle interference analysis to obtain the measured result.

Claims 21 - 26, 47, 58 - 59, 66 lack an inventive step under PCT Article 33(3) as being obvious over Sfez et al in view of Tomlinson, Jr. et al, further in view of Wang (US 6041248) or Dolfi et al (US5174298) since in the case of the former, it would have been obvious to provide frequency-encoding into Sfez et al in order to provide dimensional specificity to the measurement, or in the case of the latter, it would have been obvious in view of Dolfi et al col. 2 lines 50 - 54 to use differing frequencies in the pulse sequences of Sfez et al in order to improve the signal-to-noise ratio. In the case of Dolfi et al, optical heterodyning is used with a local oscillator to generate measurement data.

Claims 42 - 44 lack an inventive step under PCT Article 33(3) as being obvious over Sfez et al in view of Irion et al (US6390978). Whereas the former does not teach use of annular interspersed array structure, it would have been obvious in view of the latter col. 13 lines 13 - 25 to use an interspersed optic array and annular ultrasound array construct in order to provide focused ultrasound co-linear with diffused collection.

International application No-PCT/IL05/00300

Supplemental Box In case the space in any of the preceding boxes is not sufficient.	
Claims 18 - 20,38 - 39, 45 - 46, 60 - 65 meet the criteria set out in PCT Article 33 suggest using continuously chirped acoustic radiation having at least two different optical coupling and light guide lengths soas to satisfy a coherence length require untagged photons, or the adaptation of the system into a jugular vein measurement into the external ear canal.	ment for interference operation between tagged and nt device allowing insertion of at least part of the unit
Claims 1-70 meet the criteria set out in PCT Article 33(4) and thus have industria or used in industry.	I applicability because the subject matter cam be made
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REC'D 27 MAR 2006

		F	ATENT	COOPE	RATION TREA	TY	TILOS Z T TO	
rom the	NAL SEARCHI						WIPO	PCT
To: Svetlana Sht	adler					PC'	\mathbf{T}	
REINHOLD COHN AND PARTNERS P.O. BOX 4060 TEL AVIV, ISRAEL 61040			WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY			ORITY		
						(PCT Rule	43 <i>bis</i> .1)	
					Date of mailing (day/month/year)	23	MAR 2006	
Applicant's	or agent's file ref	erence			FOR FURTHER	ACTION See paragraph 2	below	
159035-5 D			T.A	al filing date	(day/month/year)	Priority date (a	lay/month/year)	
Internationa	l application No.							1
PCT/IL05/0	00300		16 March	2005 (16.03.2	2005)			
Internationa	al Patent Classific	ation (IPC)	or both natio	nai ciassilica	tion and if C			
IPC(7): A6	1B 08/00 and US	Cl.: 600/438	3					
Applicant								
OR-NIM M	IEDICAL LTD.							
1. This of	pinion contains in	dications re	lating to the	following ite	ms:			
	Box No. I	Basis of th	e opinion					ļ
	Box No. II	Priority						
	Box No. III	Non-estab	lishment of o	opinion with	regard to novelty, inve	entive step and in	ndustrial applicabil	ity
	Box No. IV		ity of invent					
	Box No. V	Reasoned applicabil	statement ur ity; citations	nder Rule 43 <i>b</i> and explanat	is.1(a)(i) with regard ions supporting such	to novelty, inver statement	itive step or indust	ial
	Box No. VI	Certain do	cuments cite	ed				
	Box No. VII			international				
	Box No. VIII	Certain ol	oservations o	on the internat	tional application			
	THER ACTIO					U. b annsidered	to be a written o	ninion of the
Interr	national Prelimin	ary Examin	ing Authori	and the chose	nade, this opinion wi except that this doe en IPEA has notified ty will not be so consi	the Internationa	here the applicant	chooses an le 66.1bis(b)
IPEA of Fo	a written reply to frm PCT/ISA/220	ogether, who or before the	ere appropri le expiration		rritten opinion of the endments, before the estimates from the priority date			submit to the tee of mailing
For f	urther options, se	e Form PCT	/ISA/220.					
3. For f	urther details, see	notes to Fo	rm PCT/ISA					
Name an	d mailing address	of the ISA	US	Date of con	pletion of this opinion	Authorized	omcer	
	Mail Stop PCT, At Commissioner for	tn: ISA/US		17 January	2006 (17.01.2006)	Marvin Lat	teef	አ. ,
	P.O. Box 1450 Alexandria, Virgin	ia 22313-145	0			Telephone 1	No. 703-308-0858	
Facsimile	Facsimile No. (571) 273-3201 Form PCT/ISA/237 (cover sheet) (April 2005)							
Form PCT	/ISA/237 (cover s	neet) (April	2003)					

International application No.

PCT/IL05/00300

Box No. I Basis of this opinion			
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1. With regard to the language, this opinion has been established on the basis of:			
the international application in the language in which it was filed			
a translation of the international application into, which is the language of a translation furnished for the puinternational search (Rules 12.3(a) and 23.1(b)).			
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a. type of material			
a sequence listing	İ		
table(s) related to the sequence listing			
b. format of material			
on paper			
in electronic form			
c. time of filing/furnishing			
contained in the international application as filed.			
filed together with the international application in electronic form.			
furnished subsequently to this Authority for the purposes of search.			
In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto or furnished, the required statements that the information in the subsequent or additional copies is identical application as filed or does not go beyond the application as filed, as appropriate, were furnished.	has been filed to that in the		
4. Additional comments:			
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Form PCT/ISA/237(Box No. I) (April 2005)

Form PCT/ISA/237 (Box No. V) (April 2005)

International application No. PCT/IL05/00300

Box No. V Reasoned statement under Rule	43 bis.1(a)(i)	with regard to novelty, inventive step or	industrial
applicability; citations and expl	anations supp	orting such statement	
. Statement			
Novelty (N)	Claims	5-8,10-35,38-39,42-48,55 - 70	YES
Novelly (14)		1-4,9,36-37,40-41,49-54	NO
			VEC
Inventive step (IS)		18-20, 38-39,45-46,60-65	YES NO
	Claims	1-17,21-37,40-44,47-59, 66-70	110
	Claims	1 - 70	YES
Industrial applicability (IA)		NONE	NO
2. Citations and explanations:			
2. Citations and explanations. Please See Continuation Sheet			
Please See Community Sheet			
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International application No. PCT/IL05/00300

Supplemental Box In case the space in any of the preceding boxes is not sufficient.	
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International application No. PCT/IL05/00300

Supplemental Box			
In case the space in any of the preceding boxes is not sufficient. Claims 18 - 20,38 - 39, 45 - 46, 60 - 65 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest using continuously chirped acoustic radiation having at least two different values of a gradient of the chirping or the selection of optical coupling and light guide lengths soas to satisfy a coherence length requirement for interference operation between tagged and untagged photons, or the adaptation of the system into a jugular vein measurement device allowing insertion of at least part of the unit into the external ear canal.			
Claims 1-70 meet the criteria set out in PCT Article 33(4) and thus have industrial applicability because the subject matter cam be made or used in industry.			